

Atty Docket: VASC 1020-2 US

REMARKS

Claims 3, 4, 8, 9, 19-23, 25-26, 38-40, 42, 74-76, 78, 102, 104 and 108 remain in this case.

Claims 3, 4, 9, 11, 23, 25, 26, 38-40, 42, 74-76, 78 and 108 have been rejected as obvious over Khosravi (U.S. Patent number 5,824,054) in view of Herzog (PCT publication number WO 98/08482). Claims 8, 41 and 77 were rejected as obvious over Khosravi '054 in view of Herzog '482 and Kropf '849. Claims 19-22 were rejected as obvious over Khosravi '054 in view of Herzog '482 and Ragheb '904. Claims 102 and 104 were rejected as obvious over Khosravi '054 in view of Herzog '482 and Hansen '352

The Cited Art

Khosravi U.S. Patent No. 5,824,054 shows a graft stent 10 made of a coiled sheet 11 of lattice or mesh to which a biocompatible graft material 12 is affixed. Graft material may have a desired permeability and may be impregnated with one or more drugs to effect a desired treatment. (Column 4, lines 61-66.) Graft stent 10 is wrapped on to itself like a roll of tape. Figures 5A-5C show placement of graft stent 10 into a body lumen 100 to treat an aneurysm 101. The graft stent 10 is expanded by a balloon 47 and is locked into its enlarged diameter configuration by teeth 15 engaging openings 16. (See figure 1 and column 5, lines 32-40.) The device is stated to be useful to "stem blood loss through an arterio-venous fistula, or provide a positive seal at the ends of a graft to reduce bypass flow." (Column 2, lines 31-35; column 3, lines 3-8.)

Herzog PCT Publication No. WO 98/08482 discloses several embodiments:

- The surface of, for example, a stent, catheter, etc. is coated with a polymeric coating containing sodium nitroprusside. The coating permits the NO to diffuse into the blood or body tissue. See page 6, last paragraph. The coating can be formed by immersing the stent, catheter, etc. into a solution or colloidal suspension including the polymer and sodium nitroprusside. See page 13, first full paragraph.
- Figure 2, page 15 discloses a stent and grooves on the inner wall. Sodium nitroprusside can be deposited in the grooves and covered by a polymer coating.
- Page 19, example 6 of Herzog discloses a metal stent with grooves along its length. A nitroprusside powder is placed in the grooves and the stent is coated with the PVC solution. The number of coatings, and thus the thickness of the PVC, can be changed to obtain the desired flux of NO.

Atty Docket: VASC 1020-2 US

Hanson U.S. Patent No. 5,399,352 discloses a drug delivery device 10 comprising a first element 4 and a second element 24. The first element comprises an elongate tubular segment 5 comprising a porous clinical vascular graft attached at each end to a severed artery 2. Tubular segment 5 includes a porous portion 28. Porous portion 28 is surrounded by second element 24. A reservoir 20 is formed between porous portion 28 and second element 24. Reservoir 20 can be non-fillable or supplied with an agent through tubing 30. See column 7, line 32-column 8, line 20. This permits the agent to be delivered into the blood flowing through tubular segment 5 so that it can pass with the blood into the interior of the artery.

Kropf U.S. Patent No. 4,760,849 discloses a planar blank which can be made into a coil spring useful as a filter for thromboses. The coil spring has apertures to facilitate ingrowth of tissue into the spring material. See column 1, lines 61-63 and column 2, lines 51-55. This reference only discloses a stent. It teaches away from adding a graft material because a stated intention of the invention is to permit tissue ingrowth through the apertures. There is no recognition that the addition of a graft material would be useful or possible.

Ragheb U.S. Patent No. 5,873,904 discloses a medical device 10 including a structure 12, typically a vascular stent 12, composed of an elastic/non-elastic, biodegradable/non-biodegradable base material 14, such as stainless steel, nitinol, polymers, etc. Stent 12 is shown to have several layers of materials coated thereon. At least one layer 18 of a bioactive material is on the surface of stent 12. An outer porous layer 20 is on layer 18 to provide controlled release of the bioactive material. A porous/non-porous layer 16 may be used between the bioactive layer 18 and stent 12. A second bioactive layer 22 may be used between porous layer 20 and bioactive layer 18; if so, an inner porous layer 24 may be used between the bioactive layers 18, 22.

The Cited Art Distinguished**Independent claim 38**

1. Independent claim 38 has been amended to specify that the coiled body extends along a generally helical path. See paragraph 0057 and figures 1E, 8 and the 9. In contrast, the structure of Khosravi does not extend along a generally helical path but rather stays in the same axial position.

2. It appears that the Examiner considers the PVC coating of Herzog to be a sleeve or coating as claimed. The applicant believes that Herzog discloses a coating. Applicant disagrees that the PVC coating of Herzog could be characterized as a sleeve as that term is used in the application and as is commonly understood. "1. The part of a garment that covers all or part of the arm. 2. Any encasement

or shell into which a piece of equipment fits." The American Heritage Dictionary of the English Language, New College Edition, Houghton Mifflin Company, 1976.

This distinction between coating a surface of a stent, coating a surface of a graft material, incorporating the agent into a graft material and locating the agent within the interior of a sleeve of graft material is highlighted in paragraph 0052 (underlining added).

"[0052] The stent grafts of Figs. 3-5C may be constructed for delivering a biologically active agent, if desired. Such covered, coiled drug delivery stents may be constructed in several ways. One way is to place one or more biologically active agents on one or both of outer and inner surfaces 124A, 124B of the sleeve of material 124 shown in Fig. 3A. A biologically active agent may also be on inner surface 124B or contained within sleeve interior 124C; such agent may be, for example, coated on the stent or may be captured between the stent and inner surface 124B. Another way is to incorporate the agent into graft material 124 to create an agent/material matrix. Such a matrix may be created by using a porous material for graft material 124. The porous graft material is then saturated with a mixture of a carrier, such as water or alcohol, and one or more agents. One way to do so is shown in Fig. 3B. A sleeve of graft material 124 has one end 124F knotted to close off that end while a syringe S is used to fill graft material 124 with the mixture M. When the mixture has fully saturated graft material 124, which is typically evident when the mixture seeps through the pores of graft material 124, the excess amounts of the mixture is drained and the now agent-laden graft material is at least partially dried. Another method is to manufacture the graft material with one or more agents interspersed therein. The agents may be, for example, microencapsulated to provide a time-release function for the agent. Time release may also be achieved by coating outer surface 124A with an appropriate biodegradable material."

Accordingly, Herzog does not disclose a sleeve as that term is used in this application so that the Examiner's position that Herzog discloses a sleeve or coating is incorrect because it equates the two terms and Herzog only discloses a coating. Also, the present application recognizes the differences between applying an agent to the surface of a sleeve, applying an agent to the surface of a stent (as in Herzog), incorporating an agent into the sleeve material (as in Khosravi), and containing the agent within the sleeve interior (as is presently claimed).

3. As discussed above, Herzog does not disclose a sleeve. Therefore it cannot disclose a sleeve interior.

4. Herzog discloses two basic embodiments: the first being a stent, catheter, etc. coated with a polymeric coating, the polymeric coating containing sodium nitroprusside (similarly the graft material of Khosravi may be impregnated with one or more drugs); the second being a stent having grooves with sodium nitroprusside deposited in the grooves and covered by a polymeric coating. The two basic embodiments are similar to one another in that they both use a polymeric coating to control the release of sodium nitroprusside, which is either incorporated into the polymeric coating or contained within grooves formed in the stent, the sodium nitroprusside being covered by and sealed by the polymeric coating.

Atty Docket: VASC 1020-2 US

There is nothing in either Herzog or Khosravi to suggest modifying Khosravi in view of Herzog to arrive at the present invention in which a dispensable, biologically active agent is within the sleeve interior and dispensable through the sleeve of material.

5. One of the important aspects of this invention is the recognition of the advantages which can be had by placing the dispensable agent within the sleeve interior. That is, the amount and composition of the agent can be easily modified according to the type of therapy without changing the basic structure of the device. Therefore, the present invention provides a much more flexible delivery platform than the prior art. Also, the amount of the agent is not limited by, for example, the amount that can be incorporated into a graft material or into a polymeric coating, or the amount that can be placed in grooves formed on a stent. This permits a presently claimed invention to dispense an agent over a much longer period of time than would be possible with conventional structures.

6. Assuming, for sake of discussion, that it would have been obvious to modify Khosravi in view of Herzog, which it would not have been, the following would, applicant submits, be the resulting structure. Instead of using graft material impregnated with one or more drugs, such as sodium nitroprusside, fine grooves would be formed in the role-of-tape type of coiled stent of Khosravi; sodium nitroprusside would then be placed in the grooves and covered with a polymeric coating through which the nitric oxide could diffuse. However, this is not what is being claimed. There is nothing in Khosravi, Herzog or the other art of record suggesting that there was any recognition that it would have been advantageous to place the agent within the sleeve interior as opposed to incorporating it into a polymeric coating or on the surface of the stent body. There is also nothing in Khosravi or Herzog suggesting replacing the role-of-tape type of coiled stent of Khosravi with a generally helical stent.

In summary, claim 38 is allowable over the cited art because:

1. Khosravi does not extend along a generally helical path;
2. Herzog discloses a coating - it does not disclose a sleeve;
3. Because Herzog does not disclose a sleeve, it cannot disclose a sleeve interior;
4. The art does not disclose or suggest a dispensable, biologically active agent within the sleeve interior, the agent being dispensable through the sleeve of material; and
5. The art lacks any recognition that it would have been advantageous to place the agent within the sleeve interior.
6. If Khosravi and Herzog were combined, the resulting structure would not be the claimed invention.

Atty Docket: VASC 1020-2 US

Independent Method Claim 74

Method claim 74 is allowable for similar reasons.

Dependent Claims

The dependent claims are directed to specific novel subfeatures of the invention and are allowable that reason is well as by depending from novel parent claims. For example, there is nothing in the cited art suggesting that the prosthesis include a sleeve interior which "is oversized relative to the coiled body so to loosely contain the coiled body" (see claims 102 and 104). The mere fact that Hanson discloses external reservoir 20 provides no meaningful guidance for modifying the combination of Khosravi and Herzog to a create open regions between the sleeve interior and the stent body of such a combination because the structure of Hanson relates to surrounding a perforated portion of a vascular graft; it has nothing to do with an endoluminal structure, such as a stent. They relate to two very different operating environments with very different operating constraints.

CONCLUSION

In light of the above remarks and the amendments to the claims and specification, applicant submits that the application is in condition for allowance and action to that end is urged. If the Examiner believes a telephone conference would aid the prosecution of this case in any way, please call the undersigned at (650) 712-0340.

Respectfully submitted,

Dated: 02 December 2004


James F. Hann, Registration No. 29,719

HAYNES BEFFEL & WOLFELD LLP
P.O. Box 366
Half Moon Bay, California 94019
Phone: 650-712-0340
Fax: 650-712-0263
JFH:pfh